UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-CV-12257-PBS Hon. Patti B. Saris
THIS DOCUMENT RELATES TO ALL ACTIONS	

DEFENDANT ASTRAZENECA PHARMACEUTICALS LP'S MOTION FOR LEAVE TO FILE A REPLY TO PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION IN LIMINE TO EXCLUDE EVIDENCE RELATING TO GUILTY PLEAS AND SAMPLING ACTIVITY

Pursuant to Local Rule 7.1(B)(3), AstraZeneca Pharmaceuticals LP ("AstraZeneca"), by its attorneys, hereby moves this Court for leave to file a reply memorandum in support of Defendant AstraZeneca Pharmaceuticals LP's Motion in Limine to Exclude Evidence Relating to Guilty Pleas and Sampling Activity.

1. Plaintiffs' Opposition raises arguments that Defendant AstraZeneca would like an opportunity to address.

2. Defendant AstraZeneca believes that a short reply will benefit the Court and assist it in determining whether the guilty pleas and sampling activity are relevant to the issues set for trial on November 6, 2006. The proposed Reply is only five pages in length and is attached as Exhibit 1.

Wherefore, Defendant AstraZeneca respectfully requests that this Motion for Leave to File a Reply memorandum in support of its Motion be GRANTED.

Dated: Boston, Massachusetts
October 18, 2006

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1

Pursuant to Local Rule 7.1(A)(2), the undersigned certifies that counsel for defendants conferred with counsel for plaintiffs on this motion and plaintiffs' counsel objected to the motion.

By: /s/ Katherine B. Schmeckpeper
Katherine B. Schmeckpeper

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered on October 18, 2006 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Katherine B. Schmeckpeper
Katherine B. Schmeckpeper

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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AstraZeneca's motion in limine to exclude evidence related to guilty pleas and sampling activity demonstrated that such evidence is so tangential to Plaintiffs' allegation of AWP "inflation" that its exclusion was appropriate, particularly in light of the prejudice and waste of time that would accompany its admission. Plaintiffs do not dispute that their expert does not attempt to account for sampling activity in his calculation of the alleged AWP "inflation." Nor do Plaintiffs dispute that there is no evidence in the record demonstrating that Massachusetts TPPs or consumers paid for a single sample. Instead, Plaintiffs manufacture an allegation that "sampling practices existed pursuant to a company policy to market Zoladex's return to practice" and that any consumers or TPPs in Massachusetts were injured as a result. No support exists for this assertion, and Plaintiffs' efforts to circumvent the authorities set forth by AstraZeneca in support of exclusion of this evidence accordingly miss the mark.

I. THERE IS NO EVIDENCE OF A COMPANY POLICY LINKING SAMPLING PRACTICES AND RETURN TO PRACTICE

In response to Defendant AstraZeneca's motion in limine, Plaintiffs rely heavily on the statement that "[t]he conduct of selling profit to physicians via the spread by abuse and manipulation of AWPs and the Medicare reimbursement formula . . . . is the conduct to which AstraZeneca pled guilty, plain and simple." (Pls.' Opp'n at 7). Plaintiffs' statement is unfounded.

First, nothing in AstraZeneca's guilty plea or plea allocution establish the existence of a link or company policy. See Transcript of the Plea and Sentencing Hearing in United States v. AstraZeneca Pharmaceuticals, LP, Criminal Action No. 03-55 (D. Del.) (government prosecutor stating "the lower [fine] multiplier [of 1.6] is appropriate here because of the lack of involvement in the illegal marketing scheme by AstraZeneca upper-level management."). Neither the plea nor the allocution makes any reference to marketing a return to practice. Neither of these documents suggests that the limited sampling conduct was pursuant to a company policy. Indeed, the term "AWP" is not mentioned in either document.

Second, the undisputed evidence adduced in discovery demonstrates that company policy was against physicians seeking reimbursement for free samples. Every AstraZeneca witness who was asked about this issue confirmed that AstraZeneca's corporate policy specifically prohibited encouraging or advising physicians to bill for free samples. See, e.g., Schmeckpeper Decl., Ex. A (Black Dep. at 31:5-15 ("I will categorically deny that [sampling billing] was a corporate policy. We never provided samples on a free basis in order to be billed back to Medicare.")); Ex. B (Buckanavage Dep. at 151:8-22 (stating that samples were never used to affect return to practice)); Ex. C (Chen Dep. at 146:8-11 (stating that he was never aware of Zeneca encouraging physicians to seek reimbursement for free samples)); Ex. D (Klein-Zignoli

Dep. at 143:8-11 ("When I initially started in urology, they made it extremely clear in training that physicians are not to bill for samples")); Ex. E. (Mastrangelo Dep. at 264:3-6 (stating that he was never aware of a time when AstraZeneca encouraged doctors to bill for free samples)); Ex. F. (Patterson Dep. at 132:16-20 ("Q. Do you recall the sales force—members of the sales force using—giving samples to physicians for which they could bill Medicare the full AWP? A. Absolutely not.")); Ex. G. (Reisenauer Dep. at 78:18-79:4 ("I know the one general rule, I mean that was echoed by both the Sales Management Department, as was [sic] the Marketing Department, was that these were for sample use only and not to be used, you know, not to be billed, you know, as retail products by the physician.")); Ex. H (Ryan Dep. at 15:14-20 ("Q: [D]id you ever discuss with Doctor Antoun whether he should bill for those samples? A: "When – no. First of all, no. But we – as policy, we state that no samples can ever be billed for. On every call, we make sure the physicians are aware of that.")).

Finally, Plaintiffs have not provided any evidence demonstrating a connection between return to practice and sampling.[1] Despite the voluminous materials attached to Plaintiffs' Opposition, none of the AstraZeneca documents or testimony connect sampling activity with efforts to market "return to practice." Recognizing this, Plaintiffs ask the Court to look beyond the limited conduct described in the plea because, according to Plaintiffs, AstraZeneca entered into a separate civil settlement with the United States and various state Medicaid programs "that must account for some other injury resulting from AstraZeneca's criminal activities." (Pls.' Opp'n at 10). As the Court is well aware, such an inference is exactly the type prohibited by

[1] In fact, the Zoladex Product Manager, Keith Patterson, whose documents and testimony Plaintiffs have liberally designated as part of their pretrial disclosures, unequivocally states that AstraZeneca did not use sampling to increase the spread between acquisition price and AWP. Schmeckpeper Decl., Ex. F (Patterson Dep. at 128:13-19).

Federal Rule of Evidence 408, which expressly forbids the admission of evidence of a civil settlement to prove either liability or the validity of a claim.[2] FED. R. EVID. 408; see McInnis v. A.M.F., Inc., 765 F.2d 240 (1st Cir. 1985) (granting new trial because district court erred in admitting evidence of plaintiff's settlement). Furthermore, such an inference is unwarranted given that the criminal plea, civil settlement, and CIA expressly do not restrict or change the AWPs reported for Zoladex, the company's pricing policies, or the company's ability to discount in sales of physicians.

In sum, there is no connection between sampling and "return to practice" except for Plaintiffs' unsubstantiated hypothesis. Despite access to AstraZeneca's sampling records and other voluminous discovery, Plaintiffs have not offered any factual support for their theory. Accordingly, this Court must decline Plaintiffs' request to substitute speculation and conjecture for admissible evidence at trial.

II. THE LACK OF EVIDENCE CONCERNING SAMPLING ACTIVITY IN MASSACHUSETTS DOES NOT JUSTIFY THE USE OF THE PLEA AS A PROXY FOR EVIDENCE THAT DOES NOT EXIST

Plaintiffs acknowledge that this trial is restricted to injury that occurred in Massachusetts. (Pls.' Opp'n at 8). Plaintiffs admit, however, that they have no specific evidence that any of the TPP members of Class 2 or Class 3 reimbursed for a sample or that any of the consumer

[2] Plaintiffs also attempt to draw a connection between the plea and marketing "return to practice" by citing documents which, according to Plaintiffs, suggest that AstraZeneca stopped discussing reimbursement with physicians as a result of the OIG investigation. As this Court is well aware, while a government investigation may encompass various topics, the final charging instrument is based upon only those charges for which the government determines it has adequate factual support. It would be entirely inappropriate for this Court to find that the limited charge of a one count violation of the PDMA can be used as evidence of other unrelated and uncharged conduct that may or may not have been the subject of the government investigation.

members of Class 3 made a co-payment for a sample. In fact, according to Plaintiffs, it would be impossible to know whether such conduct occurred. (Id. at 8 ("There is no way based on AZ's conduct that a Class 2 or Class 3 TPP would know whether it had reimbursed for a sample.")). Rather, Plaintiffs again rely on the unfounded assertion that the sampling conduct underlying the plea is indicative of a company policy to market the spread and therefore "affected all members of Class 2 and 3." (Pls.' Opp'n at 8). In the absence of either a nexus between the sample billing conduct underlying the guilty pleas and Massachusetts, or some evidence demonstrating a nationwide company policy of providing samples in order to increase "return to practice," Plaintiffs cannot be permitted to use the pleas and sampling activity as a proxy for evidence that does not exist. The admitted lack of a Massachusetts connection underscores why this evidence has no bearing on whether a Massachusetts TPP or consumer over-reimbursed for Zoladex as a result of AstraZeneca's alleged AWP "inflation."

CONCLUSION

As stated above, there is no evidence that the limited sampling conduct evidenced in the plea was widespread or pursuant to a company policy. In fact, the undisputed evidence compels the opposite conclusion. In the absence of any evidence to suggest that sample billing activity caused any injury in Massachusetts, this Court must exclude documents and testimony relating to sampling activity as irrelevant.

For the foregoing reasons, AstraZeneca respectfully requests that this Court enter an Order excluding the evidence listed in Appendix A to Defendant AstraZeneca Pharmaceuticals LP's Motion in Limine to Exclude Evidence Relating to Guilty Pleas and Sampling Activity and any evidence of sampling generally.

Dated: Boston, Massachusetts
October 18, 2006

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

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I certify that a true and correct copy of the foregoing was delivered on October 10, 2006 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Katherine B. Schmeckpeper
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